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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/602,272	02/16/96	ELLIOTT M	KIR96-01

HM22/0913

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EXAMINER	
CANELLA,K	
ART UNIT	**PAPER NUMBER**
1642	24

DATE MAILED: 09/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
08/602,272	Elliott et al
Examiner	**Group Art Unit**
Karen Canella	1642

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3 months* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *6, 8-10, 12-32, and 34-50* is/are pending in the applicat

Of the above, claim(s) *16-28 and 38-50* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *6, 8-10, 12-15, 29-32, and 34-37* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to Amendment

1. Please note that the examiner assigned to your application in the PTO has changed.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 6, 8-10, 12-15, 29-32 and 34-37 are under consideration.

Claim Rejections Maintained

4. Rejection of Claims 6, 8-10, 12-15, 29-32 and 34-37 under 35 U.S.C. 102(b) as being anticipated by WO 92/16553 as evidenced by Wolfe et al (Arthritis and Rheumatism, 1994, Vol. 4, No. 4, pp. 481-491) is maintained. Rejection of Claims 6, 8-10, 12-15, 29-32 and 34-37 under 35 U.S.C. 102(e) as being anticipated by USP 5,598,195 as evidenced by Wolfe et al, is maintained. Claims 6, 8-10, and 12-1 are drawn to methods of treating or preventing thrombosis comprising administering an anti-TNF antibody. Claims 29-32 and 34-37 are drawn to methods of decreasing plasma fibrinogen in an individual at risk of thrombosis comprising administering an anti-TNF antibody. Applicant concedes that either WO 92/16553 or USP 5,598,195 teach an antibody to TNF which recognizes an epitope containing amino acid residues 87-108 or 59-80 of human TNF alpha. Applicant conceded that either WO 92/16553 or USP 5,598,195 provide teachings on the administration of said antibodies to TNF for the neutralization of TNF in vivo and the treatment of TNF alpha related pathologies. Applicant argues that WO 92/16553 and USP 5,598,195 do not provide guidelines for the route of administration and the dosage of antibody to administer in the treatment or prevention of thrombosis or in the modulation of plasma fibrinogen in individuals at risk of thrombosis. Applicant argues that because of this deficiency, neither WO 92/16553 or USP 5,598,195 disclose the instant method of treating or preventing thrombosis or decreasing plasma fibrinogen. This has been carefully considered and not found persuasive. The instant specification teaches (pg 31, lines 17-21) a daily dosage of 0.01

to 100 mg/kg body weight. The instant specification teaches an "ordinary" dosage of 1-40 mg/kg body weight given in divided doses 1-6 times a day or in sustained release form is effective to obtain desired results. WO 92/16553 (pg. 35, lines 13-18) or USP 5,598,195 (column 36, lines 11-15) teach a daily dosage of 0.01 to 100 mg/kg body weight, and a "preferable" dose of 1-10 mg/kg body weight given in divided doses 1-6 times a day or in sustained release form is effective to obtain desired results. Thus the methods disclosed in WO 92/16553 or USP 5,598,195 to treat anti-TNF alpha related pathologies clearly anticipate the instant method of treating or preventing thrombosis as evidenced by Wolfe et al.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

September 8, 2000

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600